PATENT COOPERATION TREATY

# PCT



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference<br>331/03471 | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No.<br>PCT/IL 03/00254 | International filing date *(day/month/year)*<br>26.03.2003 | Priority date *(day/month/year)*<br>26.03.2002 |
| International Patent Classification (IPC) or both national classification and IPC<br>A61M25/00 | | |
| Applicant<br>HALPERIN, Haim | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 27.10.2003 | 23.06.2004 |
| Name and mailing address of the international preliminary examining authority:<br>European Patent Office - Gitschiner Str. 103<br>D-10958 Berlin<br>Tel. +49 30 25901 - 0<br>Fax: +49 30 25901 - 840 | Authorized Officer<br>Jameson, P<br>Telephone No. +49 30 25901-580 |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL 03/00254

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

**Description, Pages**

| | |
|---|---|
| 1-16, 18-20 | as originally filed |
| 17 | filed with telefax on 23.02.2004 |

**Claims, Numbers**

| | |
|---|---|
| 2-47 | filed with telefax on 23.02.2004 |
| 1 | filed with telefax on 19.04.2004 |

**Drawings, Sheets**

| | |
|---|---|
| 1/5-5/5 | as originally filed |

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   *(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1-47 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-47 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-47 |
| | No: | Claims | |

2. Citations and explanations

   **see separate sheet**

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: US-A-5 885 258 (BESSELINK PETRUS A ET AL) 23 March 1999 (1999-03-23)
D2: US-A-4 564 014 (CHIN ALBERT K ET AL) 14 January 1986 (1986-01-14)

**1. Independent Claim 1**

In the light of the documents cited in the international search report, it is considered that the invention as claimed in the independent claim meets the criteria mentioned in Article 33 (1) PCT, i.e. it appears to be novel, to involve an inventive step and to be industrially applicable.

**Comments**

2.1 According to the requirements of Rule 11.13(m) PCT the same feature shall be denoted by the same reference sign throughout the application. This requirement is not met in view of the use of skin 102 (page 1, 13, 18), surface 102 (page 9), arm 102 (page 10), body tissue 102 (claim 1); and catheter front inlet 134 (page 1-2, 9, 13, 14, 19, 20), catheter tip 134 (page 10, 17), port 134 (page 14, 15) and aperture 134 (claim 1).

2.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D2 is not mentioned in the description, nor are these documents identified therein.

3.3 The features of the dependent claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3.4 The vague and imprecise statement in the description on page 20 implies that the

subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

3.5 As explained below, some of the features in the apparatus dependent claims 5-12, 21-24 and 44-45 relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from these claims, contrary to the requirements of Article 6 PCT.

The impediment is not part of the apparatus and therefore the claims 5-10 defining said impediment are related to the method of using the apparatus, not to the technical features of the apparatus. Claims 11-12 relating to the period of implantation do not define a technical feature which adapts the hollow tube to be implanted for such periods. Claims 21-24 related to fluid withdrawal or exchange are dependent on claim 1, which has the text "purpose of fluid intake"; and moreover are related to a method of using the apparatus. Claims 44 and [illegible] no technical feature which adapts the extensions for either type of ves[illegible]

still be within the scope of this invention. A curved catheter 118 may be useful, for example, in fluid exchange where the surrounding tissue tends to exhibit sharp curves, for example, in alveolar tissue. By incorporating a curved catheter 118 and/or a catheter 118 that is flexible, hence allows curvature to take place, damage to the tissue surrounding an alveolus may be reduced.

Catheter 118 with balloon extensions 122, or other extension embodiments, has application, for example, as a body ingress for insulin derivatives delivered to the body using, for example, an insulin pump. Additionally or alternatively, catheter 118 may be used for lavage of a body organ, wherein sterile fluids are introduced and/or evacuated for the purpose of control of infection. In these latter two applications, catheter 118 is, for example, three or more centimeters in length, based upon the thickness of the body tissue it must traverse in order to reach its targeted fluid exchange area.

In an embodiment of the invention, catheter 118 may have a larger bore, for example 4 millimeters or larger, to accommodate evacuation of exudative material that is highly viscous. Additionally or alternatively, catheter 118 may have a narrower bore, for example one millimeter or less, in order to provide a stream of fluid entering an organ with high pressure that breaks up an infectious nidus so that it can be more efficiently evacuated from the body.

Fig. 2D illustrates still another design of balloon [illegible]ere the one or more extensions are narrow with tips 156 that press a wall [illegible]loon extensions 122 are in an expanded state. This alternative embodiment allows blood movement within the surrounding cavity even as balloon extensions 122 are expanded. Narrow tips 156 possibly provide an advantage in arterial fluid exchange when catheter 118 is used in an artery were collateral arterial blood flow is missing and/or compromised and occlusion of the artery can cause tissue damage due to lack of blood flow. Narrow tips 156 allow blood flow to proceed even as balloon extensions 122 are extended.

Fig. 3 shows another embodiment of the present invention 300 where the extensions are one or more deformable extensions 312 that push walls of vein 130 away from catheter inlet 134, removing and/or displacing blockages, for example those noted above, allowing fluid intake through catheter 118. Deformable extensions 312 have a deformation area 340 that maintains one position near catheter 118 and a second position, away from catheter 118 which pushes wall of vein 130 away from tip of catheter 134. While two end positions are provided in some embodiments of the invention, for example, using suitable mechanical stops on catheter 118, in other embodiments of the invention multiple (or continuous) intermediate

## AMENDED CLAIMS

1. Apparatus adapted to be placed through a body tissue (102) and implanted in a vein (130) for the purpose of intake of fluid through an aperture thereof, comprising:

a hollow tube (118) defining at least one aperture (134); and

at least one extension (122) operative to be at at least two positions with respect to said aperture, a first position near said aperture and a second position in which at least part of said extension extends away from said aperture, wherein if said aperture becomes blocked by an impediment, moving said at least one extension from said first position to said second position operates to displace the impediment from said aperture.

2. Apparatus according to claim 1 wherein said aperture comprises a front opening at a front end of said tube.

3. Apparatus according to claim 1, wherein said aperture comprises one or more side openings in a side of said tube.

4. Apparatus according to claim 1 wherein said aperture comprises at least one front opening at a front end of said tube and one side opening in a side of said tube.

5. Apparatus according to any of the preceding claims wherein said impediment comprises an aggregate of solid material.

6. Apparatus according to any of the preceding claims wherein said impediment is down-flow from said hollow tube.

7. Apparatus according to any of the preceding claims wherein said impediment is at least partly within said hollow tube.

8. Apparatus according to any of the preceding claims wherein said impediment comprises a venous valve.

9. Apparatus according to any of the preceding claims wherein said impediment comprises body tissue.

10. Apparatus according to claim 9 wherein said body tissue is inflamed.

11. Apparatus of any of the preceding claims wherein said hollow tube is adapted to be implanted in a vein for the purpose of unimpeded intake of fluid for a period of one or more weeks.

12. Apparatus of any of the preceding claims wherein said hollow tube is adapted to be implanted in a vein for the purpose of unimpeded intake of fluid for a period of one or more months.

13. Apparatus according to any of the preceding claims, comprising an activating mechanism.

14. Apparatus according to claim 13 wherein said activating mechanism causes said extensions to extend from said first position to said second position.

15. Apparatus according to claim 13 wherein said activating mechanism causes said extensions to extend from said second position to said first position.

16. Apparatus according to claim 13 wherein said activating mechanism comprises a locking mechanism that, when unlocked, allows said extensions to extend from said first position to said second position.

17. Apparatus according to any of claims 13-16 wherein at least a portion of said activating mechanism is external to said body tissue.

18. Apparatus according to any of claims 13-17 wherein a portion of said one or more extensions is external to said body tissue.

19. Apparatus according to any of claims 13-18 wherein the activating mechanism is manually activated.



AMENDED SHEET

20. Apparatus according to any of the preceding claims wherein the activating mechanism is automatically activated.

21. Apparatus according to any of the preceding claims adapted so that said extending of said extensions occurs prior to said intake of fluid.

22. Apparatus according to any of the preceding claims adapted so that said extending of said extensions occurs during said intake of fluid.

23. Apparatus according to any of the preceding claims adapted so that said extending of said extensions occurs following said intake of fluid.

24. Apparatus according to any of the preceding claims adapted so that at least some extending of said extensions takes place irrespective of intake of fluid.

25. Apparatus according to any of the preceding claims wherein at least part of said one or more extensions, overlaps a front end of said tube when said extensions are in a first position.

26. Apparatus according to any of the preceding claims wherein said at least one [illegible] is covered by said one or more extensions in said first position.

27. Apparatus according to any of the preceding claims wherein said apertures are arranged to be covered in said first position.

28. Apparatus according to any of the preceding claims wherein one or more of said catheter and said extensions comprise a material that prevents or retards aggregation of solids from said body fluid.

29. Apparatus according to any of the preceding claims wherein one or more of said catheter and said extensions comprise a material that prevents or retards clot formation.

30. Apparatus according to any of the preceding claims wherein one or more of said catheter and said extensions comprise a material that prevents or retards body tissue inflammatory response.

31. Apparatus according to any of the preceding claims wherein one or more of said catheter and said extensions comprise a material that prevents or retards bacteria colonization.

32. Apparatus according to any of the preceding claims wherein the one or more extensions comprise expandable elements.

33. Apparatus according to claim 32 wherein said one or more expandable elements expand when filled with expansion fluid.

34. Apparatus according to claim 33, comprising an activating mechanism including a reservoir containing expansion fluid connected to said one or more expandable element extensions.

35. Apparatus according to any of claims 33-34 wherein said expansion fluid comprises a material that affects the formation of impediments and wherein said expandable element is at least partly permeable to said material.

36. Apparatus according to any of claims 1-31 wherein the one or more extensions comprise an extension with a deformable area.

37. Apparatus according to claim 36, wherein when said deformable area deforms, said extension extends from said first position to said second position.

38. Apparatus according to claim 36 or claim 37 wherein when said extension un-extends from said second position to said first position, said deformable area returns to its pre-deformed state.

39. Apparatus according to any of claims 1-29 wherein the one or more extensions comprise resilient extensions.

40. Apparatus according to any of claims 1-29 or 36-39, comprising a sheath for selectively controlling a position to which said extensions extend.



AMENDED SHEET

41. Apparatus according to claim 40, wherein when said at least one extension exits distally from said sheath they deflect radially.

42. Apparatus according to any of claims 1-29 or 36-39, comprising an extension tube of which said extensions form a distal section, wherein axial distal motion of said extension tube causes said extensions to extend.

43. Apparatus according to claim 42, wherein a distal section of said extension tube is axially fixed to a front of said hollow tube and wherein said extension tube is slotted.

44. Apparatus according to any of the preceding claims, wherein said extensions are adapted for an arm vein.

45. Apparatus according to any of the preceding claims, wherein said extensions are adapted for a non-vein vessel.

46. Apparatus according to any of the preceding claims, wherein said positions are axially displaced.

47. Apparatus according to any of the preceding claims, wherein said positions are radially displaced.

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## Facsimile Message

| | | | |
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| PAGES: | 1+ | DATE: | April 19, 2004 |
| RE: | Application PCT/IL 03/00254, our reference 331/03471 | | |

Here is proposed amendment for claim 1:

adapted to be placed through a body tissue (102) and implanted in a purpose of intake of fluid through an aperture thereof, comprising:

a hollow tube (118) defining at least one aperture (134, 220); and

at least one extension (122, 312, 502) operative to be at at least two positions with respect to said aperture, a first position near said aperture and a second position in which at least part of said extension extends away from said aperture, wherein if said aperture is blocked by an impediment, relative movement of said at least one extension with respect to said aperture, from said first position to said second position, operates to dislodge the impediment from said aperture.

Yours sincerely,

Maier Fenster
Patent Attorney